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Mailed: FEB - 5 2004

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. Re. 34,878, which claims the human drug product STARLIX® (nateglinide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,260 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,260 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 27, 2003 (68 Fed. Reg. 9091). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,775) + 372 \\ &= 1,260 \text{ days}\end{aligned}$$

Since the regulatory review period began March 9, 1995, after the patent issue date (the original patent, U.S. Patent No. 4,816,484, issued on March 28, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

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|--------------------------|---|----------------------------|
| U.S. Patent No. | : | Re. 34,878 |
| Reissued | : | March 14, 1995 |
| Original Expiration Date | : | March 28, 2006 |
| Applicant | : | Shigeshi Toyoshima, et al. |
| Owner of Record | : | Ajinomoto Co., Inc. |
| Title | : | Hypoglycemic Agent |
| Classification | : | 514/563 |

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|------------------------------|---|------------------------|
| Product Trade Name | : | STARLIX® (nateglinide) |
| Term Extended | : | 1,260 days |
| Expiration Date of Extension | : | September 8, 2009 |

Any correspondence with respect to this matter should be addressed as follows:

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| By mail: | Commissioner for Patents Mail Stop Patent Ext. P.O. Box 1450 Alexandria, VA 22313-1450 | By FAX: (703) 872-9411 Attn: Office of Patent Legal Administration |
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
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FDA Docket No.: 01E-0367
RE: STARLIX® (nateglinide)

Attention: Claudia Grillo